MAY 2 0 2005

510(k) SUMMARY

Date Summary Prepared	April 13, 2005
Submitted by	MDS Nordion 447 March Road Ottawa, Ontario K2K 1X8 Canada Tel. (613) 592-3400 Fax. (613) 592-2006
Contact Person	Mr. Ross Kachaniwsky Director, Quality & Regulatory Affairs
Device Name	Gammacell 1000 Elite Gammacell 3000 Elan
Common Name	Blood Irradiator
Classification Name	Blood irradiators have not been classified
Legally Marketed Predicate Device	Gammacell 1000 Elite Gammacell 3000 Elan

Description of Device

The basic operation of an irradiator involves placing of the blood product into the beaker, loading the beaker into the Gammacell, closing the safety door and pressing the 'start' button. Upon start of the cycle, the unit moves the beaker to the irradiate position and rotates the blood product continuously at a uniform speed to provide a consistent dose of irradiation. Concurrently, the timer begins to count down (irradiation time is pre-programmed by the site supervisor) from the set time and when the time reaches zero, the sample returns to the unload position and the audible alarm sounds.

Intended Use of Device

To irradiate cellular blood products to inactivate T-lymphocytes in order to prevent graft versus host disease.

Summary of Technological Characteristics

The Gammacell 1000 Elite and Gammacell 3000 Elan are substantially equivalent to the previous versions of the Gammacell 1000E and 3000E (k963497).

The design change is to replace an obsolete PCB, which is programmed with embedded firmware, with a standard PC 104 board. The new board has a QNX operating system and functional software applications. There are no changes to any interlock circuits, switches or motors. The operator interface remains unchanged with the existing microprocessors and embedded firmware. There are no significant changes to the primary board for control of the power supply circuit. The control system is designed to meet the same intended use and is based on the same requirements as the current model. There are no new features.

There are no changes to the mechanical structure or shielding of the Gammacell and the outside appearance remains the same.

The irradiation source and radioactivity of the caesium-137 source(s) remains unchanged.

Safety & Effectiveness

The safety of the Gammacell is equivalent or better than the predicate device.

In terms of electrical safety, the Gammacell 1000 Elite and 3000 Elan are designed to comply with

- IEC 60601-1, Medical Electrical Equipment. Part 1; General requirements for safety, and
- IEC 60601-1-2, Medical Electrical Equipment, Part 1;General requirements for safety; Electromagnetic Compatibility – Requirements for Tests

The performance of the device was tested against a set of functional specifications in an environment that simulated, as much as possible, the actual operating environment. The functional requirements included security and safety functions, operational features, timing and counting functions, ancillary equipment such as independent backup timer and beaker rotation sensing system, operator interface, etc. Validation testing demonstrated that the device is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 0 2005

Mr. R. Kachaniwshy
Director, Quality & Regulatory Affairs
MDS Nordion
447 March Road
Ottawa, ON K2K 1X8
CANADA

Re: K050963
Trade/Device Name: Gammacell 1000 Elite
Gammacell 3000 Elan
Regulation Number: None
Unclassified
Product Code: MOT
Dated: April 15, 2005
Received: April 20, 2005

Dear Mr. Kachaniwshy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K050963

Device Name: Gammacell 1000 Elite
Gammacell 3000 Elan

Indications For Use:

To irradiate cellular blood products to inactivate T-lymphocytes in order to prevent graft versus host disease.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) - AND/OR - Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050963